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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,053	09/26/2003	Arnold R. Leiboff	461.1005	7183

22846 7590 02/05/2007
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EXAMINER

HILL, LAURA C

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/672,053

Applicant(s)

LEIBOFF, ARNOLD R.

Examiner

Laura C. Hill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17, 40-42, 44, 66-68, 78 and 80-95 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 9, 80 and 82-85 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81, 86-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 December 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 4 December 2006 with respect to claims 1, 5-7, 10, 12-17, 40-42, 66-68 and 78 have been considered but are moot in view of the new ground(s) of rejection.

Election/Restrictions

2. Examiner notes that non-elected claims 2-4 and 9 would be rejoined with the elected claims if independent claim 78 is deemed allowable and generic since these claims. However this point is rendered moot since claim 78 is rejected as discussed below.

3. Newly submitted claims 80 and 82-84 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: regarding claim 80, elected figure 6 (see response dated 21 December 2005) does not show a clamp 58 but rather this element is shown in non-elected figure 3; regarding claims 82-84, the "sewing ring" 44a in figure 6 does not have "a curved portion" as required by the claim limitation but rather has a pointed, linear portion.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 80 and 82-84 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Drawings

4. The previous objection to the drawings has been removed in view of Applicant's submissions on 4 December 2006. However, the newly submitted drawings are objected to under 37 CFR 1.83(a) because figure 6 (which was the elected species in the reply dated 21 December 2005) fails to show the "circumferentially extending notch 45" as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

5. The objection to the title has been removed in view of Applicant's amendment dated 4 December 2006. The **title has been changed** to: Intestinal Insertion Tube with Sewing Ring.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 78, 81, 86-95, 1, 5-8, 10-17, 40-42, 44, and 66-68 are rejected under 35 U.S.C. 102(b) as being anticipated by Bartholomew et al. (US 4,650,473). Regarding claims 78, 81, 87, 1, 12 Bartholomew discloses an adapter 10 comprising tubular body 11 (column 3, lines 31-32); a ridge/sewing ring 17b arranged in connection with tubular body 11 including an undercut rear surface defining a circumferentially extending notch which extends rearwardly and outwardly such that a rearward edge of the sewing ring extends rearward of a forward end of the notch (column 4, lines 17-20, figure 1), whereby a filament/thread 18 passes through the sewing ring 17b and patient tissue (column 4, lines 30-34 and lines 42-48, figure 1).

Regarding claims 85-86 Bartholomew discloses tubular body 11 has proximal end 12 adapted to be inserted into the body and distal end 13, said sewing ring 17b projects toward distal end 13 and is arranged around the circumference of body 11 (column 3, lines 32-33, figures 1-6).

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Regarding claims 88 and 68 Bartholomew discloses sewing ring 17b is monolithic (figures 1-6).

Regarding claim 89 Bartholomew discloses side arm (component having luer lock threads 15) extending from a side of body 11 and adapted to mate with an outflow tube/luer lock female nut (column 3, lines 43-48).

Regarding claim 90 Bartholomew discloses tie seat (area between ridges 17a, 17b) (figure 1).

Regarding claims 91-93 and 5-8 Bartholomew discloses an outwardly extending circumferential ridge 15a that retains nib/rolled bowel sheath 19 which in turn is secured to the body (column 3, lines 57-60, column 5, lines 26-28, figures 1-3).

Regarding claims 94-95 Bartholomew discloses sewing ring 17b is made of pliable plastic and is separate from body 11 (figure 1).

Regarding claim 10 the method of forming the device (injection molding) is not germane to the issue of patentability of the device itself. Therefore, this limitation has been given little patentable weight.

Regarding claims 13-17 Bartholomew discloses multiple triangular lips/wings 16 at proximal end 12 of body 11 and angled to facilitate insertion, wherein sewing ring 17b is arranged rearward of at least one triangular lip 16 (column 3, lines 60-67, figure 4)

Regarding claims 40-42, 44, 66 see the discussion above with respect to claims 13-17 and 89.

Regarding claims 67-68 see the discussion above with respect to claims 5-7 and 86-88.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomew et al. (US 4,650,473). Bartholomew does not expressly disclose the body 11 is transparent. However it is well known to those of ordinary skill in the art that catheter or other tubular bodies inserted into the body be transparent to monitor the contents. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the body of Bartholomew, thus providing a transparent body.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kristiansen et al. (US 5,107,856) discloses tube 14 for attaching to a body having sewing ring 42 with underlying notch for passing a suture through tissue and sewing ring. Willard (US 6,221,060) discloses a urethral device 10 having an injection molded body with a plurality of resilient anchors 20 and seals 26 to secure the device inside the body.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (hours vary).

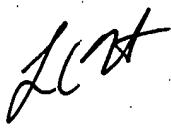
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura C. Hill
Examiner
Art Unit 3761

LCH



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER
